REMARKS

Status of the Claims

Claims 1-32, 34-36 and 39-60 are cancelled without prejudice or disclaimer of the subject matter contained therein. Claims 61-63 are added. The amendment to claim 33 is supported by the description on page 18, lines 19-23 of the specification. Claims 61 and 62 basically correspond to claims 43 and 44. Claim 63 is supported by claim 53. Claim 33 is the only independent claim in the present application. All other claims depend on claim 33 either directly or indirectly.

Claim Objections

The objection to claims 54 and 55 is moot in view of the cancellation of these claims.

Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 37 and 54 are rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth in the last paragraph on page 2 through the second paragraph on page 3 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The rejection of claim 54 is moot in view of the cancellation thereof.

Claim 37 has been amended in the manner suggested by Examiner. The amendment to claim 37 is a non-narrowing claim amendment.

In view of the amendment to claim 37 and in view of the cancellation of claim 54, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, second paragraph are respectfully requested.

Rejection of Claims 33-44 and 49-60 Under 35 U.S.C. 102(a) Over JP 2000-44602 to Sakai et al.

Claims 33-44 and 49-60 are rejected by the Examiner under 35 U.S.C. 102(a) over JP 2000-44602 to Sakai et al. [newly cited] for the reasons set forth on page 4 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

JP 2000-44602 Sakai et al. is effective as a reference as of its publication date, which is February 15, 2000. The present invention is supported by JP 11-234,262 filed August 20, 1999. Thus, this rejection may be readily removed by the filing of a certified English translation of the priority document. A certified English translation of this priority document is attached hereto.

Rejection of Claims 53-60 Under 35 U.S.C. 102(e) Over U.S. Patent 6,573,250 to Umeda et al.

Claims 53-60 are rejected by the Examiner under 35 U.S.C. 102(e) over U.S. Patent 6,573,250 Umeda et al. [newly cited] for the reasons set forth on page 4, last paragraph, through page 5 of the Office Action. This rejection is moot in view of the cancellation of claims 53-60.

Rejection of Claims 53-60 Under 35 U.S.C. 102(a) and 102(e) Over U.S. Patent 6,054,577 to Sakai et al. and Under 35 U.S.C. 102(b) Over the Corresponding Reference to Sakai et al. (WO 96/34004)

Claims 53-60 are rejected by the Examiner under 35 U.S.C. 102(a) and 102(e) over U.S. Patent 6,054,577 to Sakai et al. and under 35 U.S.C. 102(b) over the corresponding reference to Sakai et al. (WO 96/34004) [newly cited] for the reasons set forth on page 5 of the Office Action. This rejection is moot in view of the cancellation of claims 53-60.

Rejection of Claims 33-44 and 53-60 Under 35 U.S.C. 103(a) Over WO 96/34004 to Sakai et al. and JP 1-313433 to Hoshino et al.

Claims 33-44 and 53-60 are rejected by the Examiner under 35 U.S.C. 103(a) over WO 96/34004 to Sakai et al. and JP 1-313433 to Hoshino et al. [newly cited] for the reasons set forth on page 6 of the Office Action. The Examiner alleges that it would obvious to use a fucoidan such as taught by Sakai as an anti-HIV agent. The Examiner relies on the dosage range taught by Hoshino because the fucoidans from Phaeophyta are allegedly taught to be functional equivalents. The Examiner also alleges that the cytokine regulation appears to be the mechanism by which the agent acts upon a human when administered and would naturally flow from the suggestion in the prior art. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The present invention as recited in claim 33, as amended, relates to a method of treating autoimmune disease, anemia, diabetes, septic shock, inflammatory enteropathy, chronic articular rheumatism, multiple sclerosis, uveitis or an allergic disease, wherein the method comprises administering a fucoidan

derived from *Kjellmaniella crassifolia* and/or a degradation product thereof to a subject in need thereof. Accordingly, claim 33 relates to a method of treatment using a fucoidan derived from *Kjellmaniella crassifolia* for a particular disease.

U.S. Patent 6,054,577 [corresponding to WO 96/34004] at col. 1, lines 16-20 provides the following description:

> There has been reported that fucoidan, which is a sulfated polysaccharide contained in brown algae (Phaeophyta), has various biological activities including anticoagulant, lipemia-clearing, antitumor, cancerous metastasis-inhibitory and anti-AIDS virus infection effects.

U.S. Patent 6,054,577 at col. 34, lines 35-38 provides the following description:

> Furthermore, it is expected that the physiological activities of the sugar compounds of the present invention make them applicable to anticancer, cancerous metastasis-inhibitory and antiviral drugs.

The above-mentioned teachings relied upon by the Examiner do not support an argument that fucoidan is effective for the treatment of any disease requiring regulation of cytokine production. Thus, the Examiner's rejection is without factual or legal basis and the Examiner has not established a prima facie case of obviousness.

Furthermore, the Hoshino reference does not teach or suggest that fucoidan is generally effective for the treatment of a disease requiring regulation of cytokine production. The claimed therapeutic effects are not expected based on the combined disclosures of Sakai and Hoshino.

Accordingly, claim 33 relates to a method of treatment using a fucoidan derived from *Kjellmaniella crassifolia* for a particular disease. The claimed therapeutic effects are not expected based on the disclosures of Sakai and Hoshino. Thus, the prior art rejection of the present invention over Sakai and Hoshino should be withdrawn by the Examiner.

Rejection of Claims 33-44 and 53-60 Under 35 U.S.C. 103(a) Over WO 96/34004 to Sakai et al. and McCaffrey et al.

Claims 33-44 and 53-60 are rejected by the Examiner under 35 U.S.C. 103(a) over WO 96/34004 to Sakai et al. and McCaffrey et al. [newly cited journal article not JP 1-313433] for the reasons set forth on page 7 of the Office Action. See paragraphs 5-6 above regarding WO 96/34004. The Examiner alleges that it would obvious to use a fucoidan such as taught by Sakai for the treatment of atherosclerosis. The Examiner alleges that there would be an expectation of success to use fucoidans for such treatment because McCaffrey et al. teaches that fucoidans from Phaeophyta are functional equivalents. The Examiner also alleges that the cytokine regulation appears to be the mechanism by which the agent acts upon a human when administered and would naturally flow from the suggestion in the prior art. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Claim 33 has been amended so that the disease to be treated does not encompass atherosclerosis. Thus, claim 33, as amended, is not suggested over Sakai and McCaffrey. Accordingly, this rejection should be withdrawn by the Examiner.

Rejection of Claims 33-44 and 49-60 Under 35 U.S.C. 103(a) Over WO 96/34004 to Sakai et al. and JP 11-21247

Claims 33-44 and 49-60 are rejected by the Examiner under 35 U.S.C. 103(a) over WO 96/34004 to Sakai et al. and JP 11-21247 [newly cited] for the reasons set forth on page 8 of the Office Action. See paragraphs 5-7 above regarding WO 96/34004. The Examiner alleges that it would obvious to use a fucoidan such as taught by Sakai for the percutaneous treatment of allergic diseases. The Examiner alleges that there would be an expectation of success to use fucoidans for such treatment because JP 11-21247 teaches that fucoidans from Phaeophyta are functional equivalents. The Examiner also alleges that the cytokine regulation appears to be the mechanism by which the agent acts upon a human when administered and would naturally flow from the suggestion in the prior art. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Paragraphs [0005]-[0007] of JP '247 describe that screening of a plant extract as a sample was carried out using, as indices, hyaluronic acid synthesis promoting action of rat epidermal cells, hyaluronidase activity inhibitory action, and histamine release suppressive action of mass cells. As a result, the fucoidans extracted from Laminariales and Sargassum belonging to Phaeophyceae had weaker effects, showing that the effects of the present invention are specific to the fucoidan derived from a specified marine alga recited in the claim. Also, JP '247 teaches that the fucoidan derived from *Laminaria japonica* and the fucoidan

derived from Sargassum do not have hyaluronic acid synthesis promoting action (Test Example 1), that these fucoidans have low hyaluronidase activity inhibitory action (Test Example 2), and that these fucoidans have low histamine release suppressive action (Test Example 3). These disclosures teach against the effectiveness of the treatment of an allergic disease of the fucoidan derived from *Kjellmaniella crassifolia* (Laminariales).

In contrast to the teachings of JP '247, Examples 7 and 8 of the present application teach that IgE antibody titer is suppressed by administering to a rat, which is antigen-sensitized by ovalbumin, the fucoidan derived from *Kjellmaniella crassifolia* together with drinking water. See page 62, line 21 to page 65, Table 2 of the present specification. In other words, since the fucoidan of the present invention shows a suppressive action for IgE antibody production in a symptom sensitized with an antigen via oral administration, the fucoidan is more effective for the treatment of an allergic disease than the fucoidan disclosed in the JP '247 reference. Accordingly, the effects of the present invention are not taught or suggested by Sakai and JP '247 and the rejection should be withdrawn.

Obviousness-Type Double Patenting Rejection

Claims 33 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 11 of U.S. Patent 6,593,311 for the reasons in the last paragraph on page 9 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The rejection with respect to claim 39 is moot in view of the cancellation thereof.

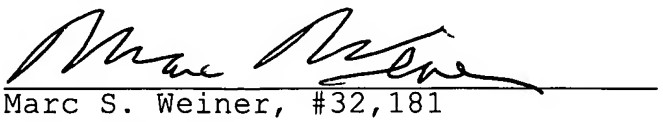
Claim 33 has been amended so that it does not encompass a disease associated with apoptotic induction. Thus, this rejection should be withdrawn.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three month extension of time for filing a reply in connection with the present application, and the required fee of $980.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

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